REMARKS

REJECTION UNDER 35 USC §112

The examiner rejects claims 1-4 under 35 USC §112, ¶2 for indefiniteness. Applicants respectfully submit that the present amendments are sufficient to overcome this rejection with regard to the process steps and the IL-6 levels. The term septic disorders, as indicated in the specification, is one well known in the medical arts, and refers to "clinical states in which agents causing inflammation, eg. bacteria, start from a focus and reach the blood stream, which initiates a wide range of subjective and objective pathological manifestations." Specification p.1:19-22. Septic disorders are clinically recognized and known, and one of skill in the art would easily understand the scope of the present claims. The clinical category may be broad, and yet it is not indefinite. Applicants respectfully request that the examiner withdraw the rejection under 35 USC §112.

REJECTION UNDER 35 USC §101

The examiner rejects claim 7 under 35 USC §101, stating that "waiting to establish the IL-6 level in a patient with sepsis will be injurious to the patient." Office Action, p.3 (citing Stenzel et al., US 6,235,281, Fig. 1A). Applicants respectfully traverse this rejection.

The theory on which the examiner applies §101 to claim 7 is unclear from the rejection, though it appears that the examiner is suggesting the present invention would not be "useful" in practice, given the alleged danger. Applicants respectfully point out

that the present specification establishes the beneficial nature of the presently claimed invention, and further, that Stenzel does not suggest that "waiting to establish the IL-6 level" would be injurious. Figure 1A of Stenzel "shows the mortality in the population with [IL-6]>1000 pg/ml in the various treatment groups." Col.4:16-17. All 36 of these patients had their IL-6 levels measured "before the start of therapy," col.4:9-12, thus indicating that Stenzel does *not* consider delay of treatment for purposes of measuring IL-6 levels to be injurious. Additionally, Stenzel indicates that anti-TNF antibodies or placebos were administered nine times over a period of three days, in addition to standard septicemia therapy, col.3:52-col.4:8, clearly demonstrating that measurement periods as in the present claims would not be considered injurious.

Applicants respectfully request that the rejection under 35 USC §101 be withdrawn.

REJECTION UNDER 35 USC §102(E)

Claims 1-2 and 4 are rejected under 35 USC §102(e) as anticipated by Stenzel et al., US 6,235,281. This rejection is respectfully traversed based on the present amendments. Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 USC §102(E)

The examiner's rejection of claims 3 and 5-7 under 35 USC §103(a) based on Stenzel et al., US 6,235,281, WO 95/20978, in view of Kragsbjerg et al. has been maintained. Applicants again respectfully traverse this rejection.

In response to our previous arguments, the examiner states that claim 1 "does not actually require any measurement of IL-6 in the 30 min." Office Action, p.5. This deficiency has been remedied. The examiner also reasons that an increase in the IL-6 level is inherent in any septicemia patient having IL-6 levels of 500 pg/ml and more, as IL-6 is not detectable in healthy individuals. *Ibid.* In the present claims, IL-6 levels must be "determined" at two different times. Stenzel mentions only a single measurement prior to therapy, and does not fairly suggest a measurement taken while the patients are healthy and asymptomatic, as the examiner's reasoning would require.

The examiner's citation of Kragsbjerg, that "significantly higher levels of cytokines IL-6, IL-8 and TNF-alpha were found in patients with severe sepsis compared to the levels found in patients with less severe illness," *id.*, at 6 (citing Kragsbjerg, p.396, ¶2), does not address the relative merits of treatment where higher IL-6 levels are determined in *a single individual* after passage of a period of time. The cited language from Kragsbjerg, rather, only states that patients with severe sepsis had higher levels of cytokines than patients with less severe sepsis. Such a statement *only* establishes that increasingly severe sepsis correllates with increases in these cytokines. The citation cannot fairly be interpreted to suggest that treatment will be more successful in more severe cases than less severe ones. As the reference does not mention measuring for an increase over time in an *individual* patient, it is not seen how it can fairly suggest there to be an advantage in treating individual patients demonstrating such an increase.

For the above reasons, applicants respectfully submit that the combined

disclosure of the cited references does not fairly disclose all elements of the present invention, and request that the rejection under 35 USC §103(a) be withdrawn.

DOUBLE PATENTING REJECTION

Applicants again respectfully traverse the examiner's rejection of claims 1-7 under the doctrine of obviousness-type double patenting based on claims 1-3 of Stenzel et al., in view of Kragsbjerg et al. For the reasons stated in the directly preceeding section, applicants submit that the present claims are not obvious over these references, and request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

Please find attached a check for $ 100.00 for a one month extension of time.

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Respectfully submitted,
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